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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,316	12/20/2001	Winston J. Brill	APF 02.05	6832

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EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,316

Applicant(s)

BRILL ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 4, drawn to a method of transforming animal cells *in vitro*, classified in class 435, subclass 455.
- II. Claims 5-6, drawn to methods of transforming animal cells *in vivo*, classified in class 800, subclass 25.
- III. Claim 10, drawn to somatic cells of non-human animals transformed *in vitro*, classified in class 435, subclass 325.
- IV. Claims 11 and 16, drawn to a non-human comprising transformed somatic cells, classified in class 800, subclass 13.

Claims 1-3, 7-9 and 12-15 are generic to Groups I and II and will be examined to the extent of either group, if elected.

Inventions I and II are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods that are not capable of use together and have different modes of operation and different functions. The method of Groups I and II are materially different methods requiring different reagents having different chemical structures and different technical considerations. For example, the

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method of Group I is directed to a method of transforming animal cells *in vitro* while the method of Group II is directed to a method transforming animal cells *in vivo*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirement, and different classification, restriction for examination purposes as indicated is proper.

Inventions III and IV are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are products that are not capable of use together and have different functions. The products of Groups III and IV are chemically different and can be used in different methods. For example the *in vitro* cells of Group III can be used to produce a protein while the non-human animal of Group IV can be used as a model of disease. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirement, and different classification, restriction for examination purposes as indicated is proper.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the *in vitro* cells of Group III can be made by a

different process than the process of Group I. For example, the cells of Group III can be transformed using liposomes such that the cells comprise an exogenous genetic construction that expresses a gene product. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions I and IV are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. The method of Group I can be used to transform animal cells *in vitro* while the non-human animal of Group IV can be used as a disease model. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the non-human animal of Group IV can be made by a different process than the process of Group II. For example, the animal of Group IV can be made by microinjecting a genetic construction that expresses a gene

product into a fertilized oocyte. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II and III are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together and have different functions. The method of Group II can be used to transform animal cells *in vivo* while the *in vitro* animal cells of Group III can be to produce a protein. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirement, restriction for examination purposes as indicated is proper.

A telephone call was made to Thomas McCracken on 6/2/03 to request an oral election to the above restriction requirement, but did not result in an election being made. It would appear that the telephone number of Mr. McCracken in the PTO records is incorrect as the Examiner attempted to contact but could not reach Mr. McCracken.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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PETER PARAS
PATENT EXAMINER

